DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

June 30, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 39

Jane Hawley Stevens
Owner
Nature's Acres
E8984 Weinke Road
North Freedom, Wisconsin 53951

Dear Ms. Hawley Stevens:

A recent inspection of your drug manufacturing facility located in North Freedom, WI, revealed that your firm manufactures a number of cosmetic type products. Medical claims in the labeling of the products listed below cause them to be drugs within the meaning of Section 201(g)(1)(B) and (C) of the Federal Food, Drug and Cosmetic Act (the Act).

The following products are drugs within the meaning of Act:

"Herb Infused Body Oil Rosemary -- Comfrey"
"Herb Infused Body Oil Lemon -- Eucalyptus -- Calendula"
"Herb Infused Body Oil Wisconsin Violet"
"Moisture Cream Rose Comfrey"
"Moisture Cream Unscented Comfrey"
"Facial Toner"
"Lip Balm Lemon Aloe"
"Lip Balm Orange Calendula"

"Herbal Salve"
"Lavender -- Vitamin E Hand Made Soap"
"Almond -- Sage Scrub Hand Made Soap"
"Herbal Bath Salts Uplifting Blend"
"Herbal Bath Salts Tonic Blend"
"Herbal Bath Salts Soothing Blend"

Our inspection also revealed that your facility is not operated in compliance with Good Manufacturing Practices for Finished Pharmaceuticals (GMP), Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211). Serious deviations from GMP documented at your facility include, but are not limited to, the following:

A. Failure to assign lot numbers to each lot manufactured.

B. Failure to assign an expiration date for products for which there is no stability data to support a 3-year expiration period.

C. Failure to test incoming raw materials, or in lieu of testing, to receive a valid Certificate of Analysis from the supplier.

D. Failure to test finished products prior to releasing the lot.

E. Failure to establish a quality control unit.

F. Failure to establish a complaint file.

G. Failure to establish written Standard Operating Procedures or product specifications.

Drugs that are manufactured in a facility that is not operated in compliance with GMP are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

In addition, the labeling for "Facial Toner" bears claims for its use as an antiseptic cleanser for skin blemishes. This product contains hazel, elderflower, yarrow and

calendula. Because of the label claims, it is subject to the Final Rule on over-the-counter (OTC) acne drug products (21 CFR 333, Subpart D). The product fails to meet the requirements of the Final Rule in that the ingredients are not permitted for acne. Further, the labeling fails to comply with the Final Rule with respect to directions for use and required warnings.

The "Almond--Sage Scrub Hand Made Soap" contains saponified coconut oil, olive oil, cocoa butter, water, almonds, essential oil of sage, OCIA organic sage, and benzoin absolute. We are unaware of any evidence that the combination of ingredients found in this product is generally recognized as safe and effective as an antiseptic.

Based on the above claims, the "Facial Toner" and "Almond--Sage Scrub Hand Made Soap" products are "new drugs" as described in Section 201(p) of the Act, and may not be legally marketed in the United States since they are not subject to approved New Drug Applications [Section 505(b) of the Act]. The "Facial Toner" is also misbranded [Sections 502(f)(1) and 502(f)(2)] because the labeling fails to bear adequate directions for use and warnings required by the Final Rule on acne drug products.

The "Almond--Sage Scrub Hand Made Soap" is also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use as an antiseptic.

All of the drug products you manufacture are misbranded under Section 502(o) of the Act because they have been manufactured in a facility that has not been registered with the FDA as required under Section 510(b) of the Act, and the drug products have not been drug listed with the FDA as required under Section 510(j) of the Act.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering award of contracts.

Additionally, pending NDA, ANDA or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

LRM/ccl